

ENDOVASCULAR TREATMENT OF THE THORACIC AORTA

Patient information



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Introduction

This brochure is intended to provide basic information about thoracic aortic disease and to assist you in making an informed decision about your treatment options. If you have any questions or concerns about the diagnosis or treatment of your medical condition, please talk to your doctor. A glossary of medical terms has also been included starting on page 28. Any words that are bold throughout the text can be found in the glossary.

As with any surgery or medical procedure, the best resource for information and advice is your doctor. We hope this information will be helpful to you and your family.

Thoracic aortic disease or injury

The **aorta** is the largest blood vessel in the body. It carries blood from the heart to the rest of the body through smaller branched arteries. The **thoracic aorta** is the section of the vessel located within the chest. The **aortic arch** is the top section of the thoracic aorta and connects the **ascending aorta** with the **descending aorta**.

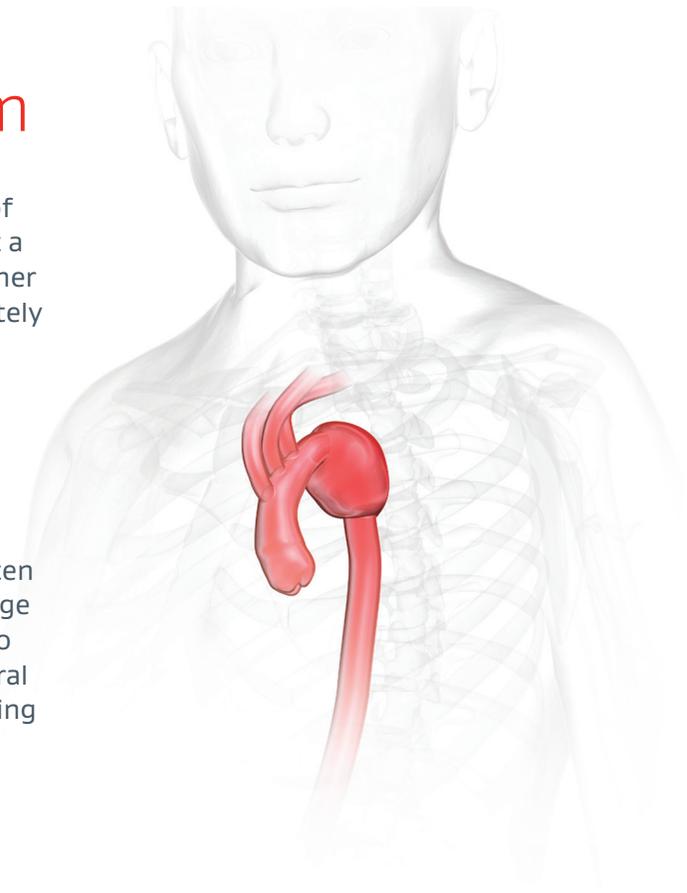
There are many different diseases and injuries of the thoracic aorta. The most common categories are **thoracic aortic aneurysm (TAA)**, **traumatic aortic transection** and **aortic dissection**. The disease or injury can sometimes require coverage of the **left subclavian artery (LSA)**. When the LSA is covered, blood flow to the LSA can be maintained through an open surgical procedure called LSA revascularization. The LSA provides blood flow to the left arm and head.

Thoracic aortic aneurysm

An **aneurysm** is a ballooning (thinning and enlarging) of the aorta caused by continuous blood pressure against a weakened area. Over time an aneurysm may grow, further weakening the wall of the aorta, or it can burst completely causing **rupture**, which is bleeding inside the body.

A thoracic aortic aneurysm (TAA) is the swelling or ballooning of the thoracic aorta.

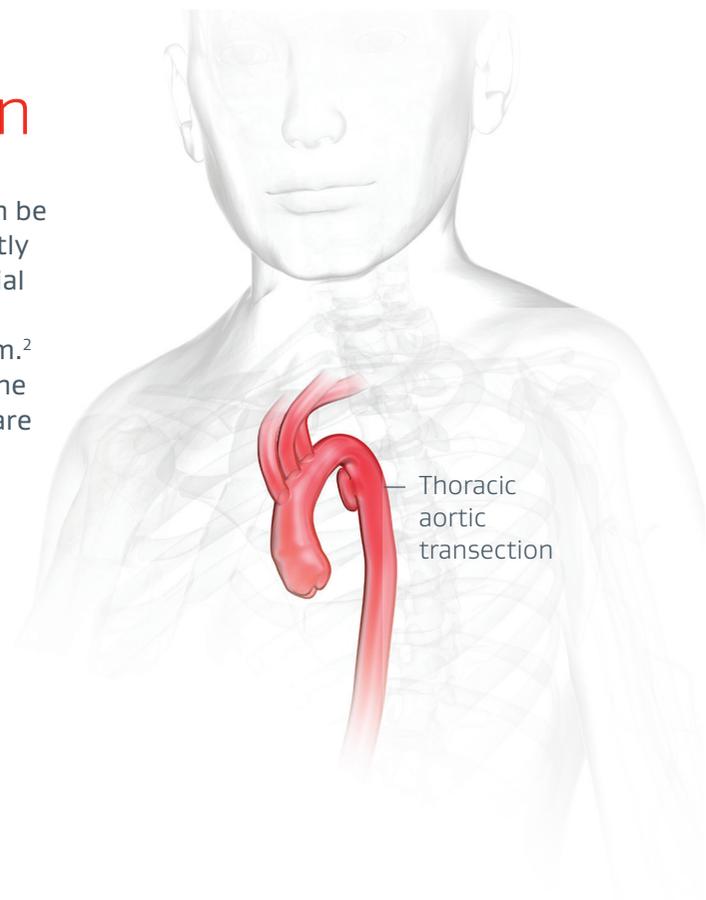
Thoracic aortic aneurysms (TAA) are rare, occurring in approximately 53 cases per every 1,000,000 people. Thoracic aortic aneurysms are known to occur more often in men than women, and the risk increases above the age of 50. Screening is especially recommended in men who have ever smoked and are over the age of 65. The natural history of aneurysm is an increase in sac diameter leading to eventual rupture.¹



Thoracic aortic transection

A transection is a tear in the wall of the aorta. This tear can be complete which results in internal bleeding and is frequently fatal. If the tear is not complete, but rather small or a partial tear, this results in a weakened section in the aorta and potentially a ballooning of the aorta much like an aneurysm.² This condition, if not treated, could result in a rupture of the aorta leading to internal bleeding. Ruptured transections are frequently fatal.

Transections most commonly occur in accidents such as motor vehicle accidents, being hit by a motor vehicle or falls from heights. Transections most commonly occur in the descending aorta but can occur in other places within the aorta.³

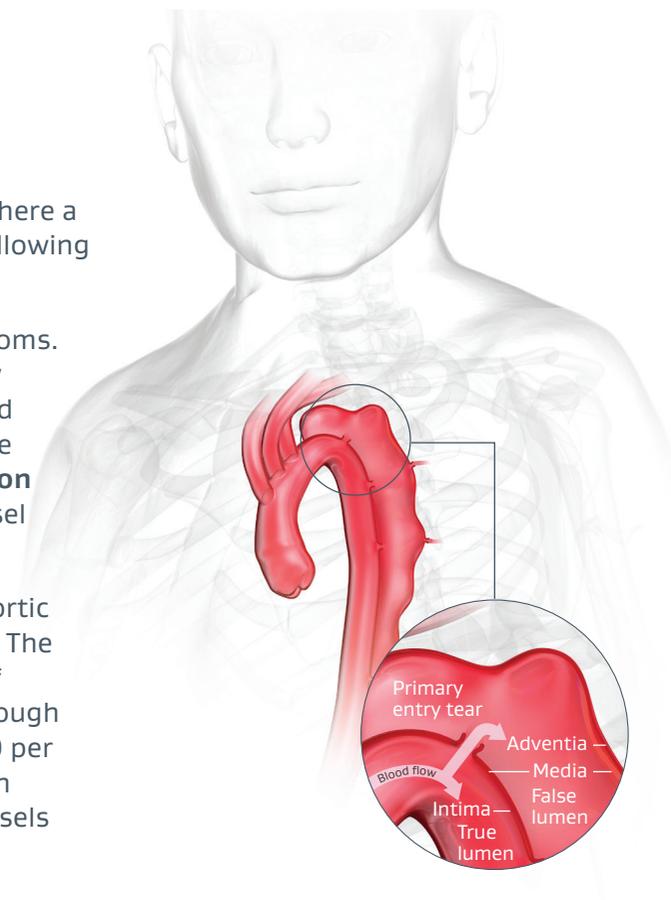


Aortic dissection

An aortic dissection is a disease in the thoracic aorta where a small tear occurs in the inner layer of the **aortic wall**, allowing blood to flow between the layers of the aortic wall.

An **acute aortic dissection** is a sudden onset of symptoms. As aortic dissections age and become **chronic**, the flow of blood between the layers of the aortic wall could lead to a ballooning of the outer layer of the aorta, much like an aneurysm. If there is a risk of rupture or **malperfusion** (loss of blood flow to vital organs caused by blood vessel obstruction), treatment may be required.⁴

Thoracic aortic dissection (TAD) is the most common aortic catastrophe requiring immediate surgical intervention. The exact population incidence is unknown as up to 30% of aortic dissections may not be clinically diagnosed, although published figures range from 5-30 cases per 1,000,000 per year. Common complications associated with dissection are rupture and blood flow obstruction into branch vessels causing a lack of blood flow to an organ or leg(s).⁵⁻⁸





Causes

Over time, weakening of the aorta due to vascular disease, injury (trauma) or a genetic (hereditary) defect of the tissue within the aortic wall can cause thoracic aorta conditions that require treatment.

Risk factors for developing thoracic aortic disease include:

- Heredity (family history)
- Smoking
- High blood pressure
- Heart disease



Symptoms

Many people do not experience any symptoms when thoracic disease is present. When symptoms do occur, pain is most commonly experienced. This can occur in the chest or back area, shoulders, neck and abdomen. Some patients describe the pain as anything from mild to severe, or a tenderness in the mid or upper chest, back or shoulders.

Diagnosis of transections is often not based on symptoms, but rather on the fact that the patient was in an accident.

An acute aortic dissection may involve a sudden onset of symptoms, which may include chest pain often described as severe and tearing along with cold sweats. The pain may be localized to the front or back of the chest. Typically, the pain moves as the dissection worsens. Other symptoms and signs of both acute and chronic aortic dissections depend on the branch vessels involved and the effect on nearby organs.

Your doctor may discover thoracic disease during a routine physical exam or a medical test such as a **CT (computed tomography) scan** or **Magnetic Resonance Imaging (MRI)**.

Treatment options

The size and location of the disease or injury and your general health influence which treatment your doctor recommends. When the disease or injury is small, or has a potentially low risk to your health, your doctor may only recommend periodic check-ups to monitor your condition. However, a larger or rapidly growing disease or injury poses more risk of rupture and may require treatment. The risk of rupture increases with size of the disease or injury and high blood pressure.

If your doctor feels treatment is necessary, two primary options are available: Open surgical repair and **endovascular repair**. Endovascular repair can be completed using one of two primary options: Non-branched endovascular repair (non-branched TEVAR) and branched endovascular repair (branched TEVAR).

Open surgical repair

Open surgical repair is an operation to remove the diseased or injured portion of the aorta when it is considered dangerous and at risk for rupture. During this type of operation, the doctor makes an incision in the chest to repair the aorta by replacing the diseased or injured section with a **synthetic graft** that is sewn into the aorta. This procedure requires stopping blood flow through the aorta while the graft is being put into place.

Non-branched thoracic endovascular repair (Non-branched TEVAR)

Non-branched thoracic endovascular repair involves sealing off the disease or injury by placing a non-branched stent-graft inside the portion of the affected aorta, making a new path for blood flow. With non-branched TEVAR, the graft sometimes covers the left subclavian artery (LSA). To maintain blood flow into the LSA, the LSA must be moved or bypassed to another branch vessel through an open surgical LSA revascularization procedure. The open surgical LSA revascularization procedure can be performed before the TEVAR procedure or at the same time.

Branched thoracic endovascular repair (Branched TEVAR)

Branched TEVAR allows for endovascular repair of the descending thoracic aorta that includes the left subclavian artery. With branched TEVAR, blood flow to the LSA is maintained through a branch device (*Figure 1*) avoiding the open surgical LSA revascularization procedure.

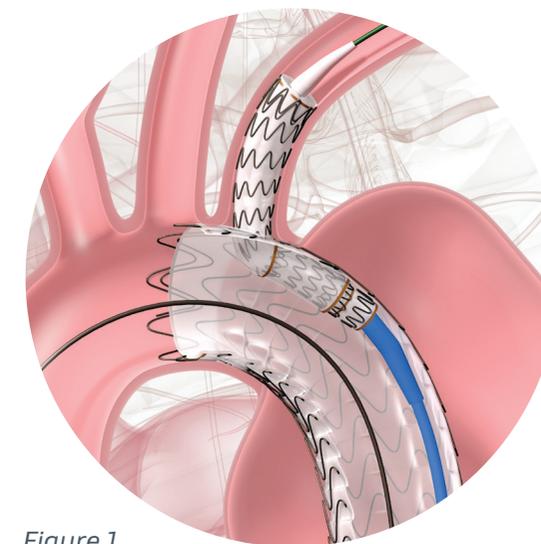


Figure 1.

GORE® TAG® Thoracic Branch Endoprosthesis

The GORE® TAG® Thoracic Branch Endoprosthesis (TBE) is an implantable branched **stent graft** designed for branched TEVAR of the descending thoracic aorta requiring placement into an area of the arch that includes the left subclavian artery in patients who are at high risk for debranching subclavian procedures. It consists of at least two components which line the thoracic aorta and the left subclavian artery. The devices allow blood to flow into the left subclavian artery and the rest of the aorta while preventing blood from flowing to the affected area and does not require an open surgical procedure. The device extends from the left subclavian artery, including a portion of the aortic arch, to the descending thoracic aorta.

The GORE® TAG® Thoracic Branch Endoprosthesis is made of expanded polytetrafluoroethylene (ePTFE) with an outer metallic support structure known as a stent. See *Figure 2* for an image depicting the GORE® TAG® Thoracic Branch Endoprosthesis.

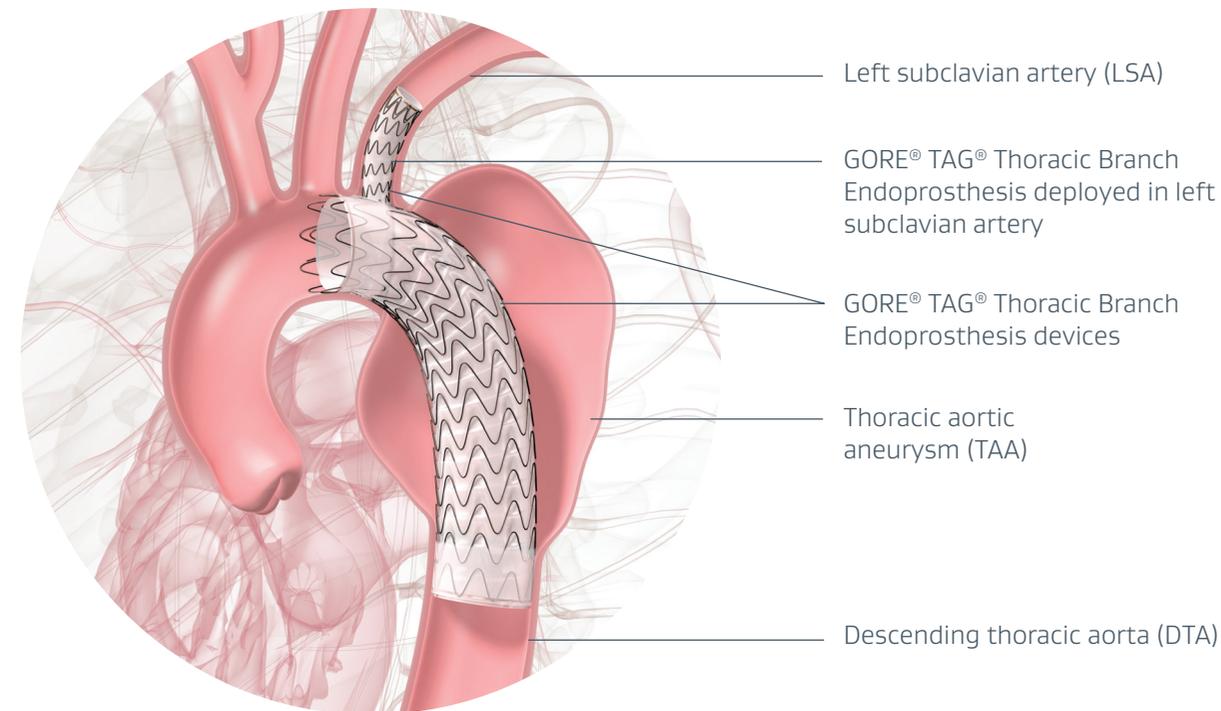


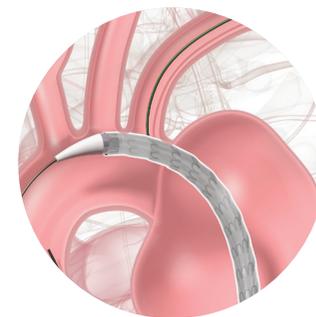
Figure 2. GORE® TAG® Thoracic Branch Endoprosthesis deployed in the left subclavian artery and the descending thoracic aorta.

GORE® TAG® Thoracic Branch Endoprosthesis procedure

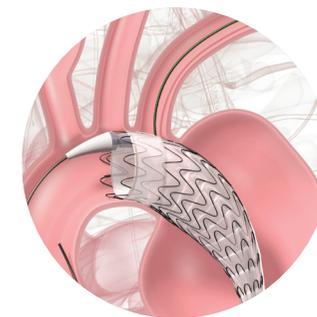
The procedure for implanting the GORE® TAG® Thoracic Branch Endoprosthesis consists of the delivery of the stent grafts into the aorta and the left subclavian artery. While the endovascular procedure is similar for trauma or dissection repair, below is an example of the steps included in an aneurysm repair.

The main body stent graft is implanted using **fluoroscopy**, or real-time x-ray images, and is viewed on a monitor following these steps:

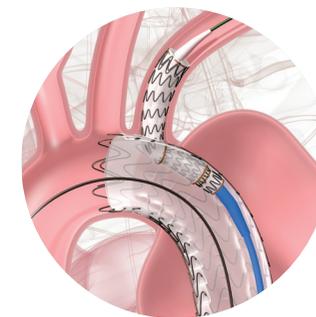
1. The **delivery catheter**, which contains the stent graft, is inserted into the **femoral** or **iliac artery** and carefully guided through the abdomen into the chest to the site of the diseased or injured aorta.
2. Once the stent graft is correctly positioned in the aorta and aligned with the left subclavian artery, it is released, or deployed, from the delivery catheter. The device self-expands to the diameter of the aorta and the delivery catheter is withdrawn from the body.
3. A second, smaller stent graft is inserted into the femoral or iliac artery and positioned through the opening of the first stent graft into the left subclavian artery.



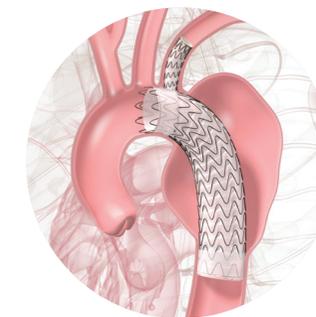
Positioning aortic component at left subclavian artery



Deployment of aortic component



Positioning of side branch component into left subclavian artery



Final GORE® TAG® Thoracic Branch Endoprosthesis system

4. Once the second stent graft is correctly positioned within the left subclavian artery, it is released, or deployed, from the delivery catheter. The delivery catheter is then removed.
5. Following deployment, an endovascular balloon may be inflated inside the device to aid the device in opening completely, allowing the device to achieve better seal.

In some cases, it may be necessary to utilize an additional component to extend higher into the aortic arch or lower into the descending aorta.



Clinical data summary

The GORE® TAG® Thoracic Branch Endoprosthesis was evaluated for safety and performance in a multi-center pivotal study. A total of 244 patients were enrolled at 40 sites in the United States (U.S.). Patients are being followed for five years after implant. Patient groups were separated by type of injury (aneurysm, dissection, traumatic transection and other isolated lesions). The primary purpose of the study was to measure the device technical success and safety events for aneurysm patients. Only one patient group had a performance goal to meet while the other three groups only collected the information.

Of the aneurysm patients treated with the GORE® TAG® Thoracic Branch Endoprosthesis, 83.8% remained free from device technical failure and safety events followed out to one year. The results from the other patient groups treated in this study also demonstrated the safety and effectiveness for the TBE Device. No new safety risks were identified with the use of the GORE® TAG® Thoracic Branch Endoprosthesis.

This study demonstrated that the GORE® TAG® Thoracic Branch Endoprosthesis Device is safe and effective as a treatment option for the endovascular treatment of aortic disease in the descending thoracic aorta while maintaining blood flow to the left arm and head.

Risks

Like surgery, endovascular repair with a stent graft comes with potential risks. It is important to discuss the risks and benefits of treatment with your doctor.

The GORE® TAG® Thoracic Branch Endoprosthesis may be associated with an increased rate of stroke, **endoleak** and new dissection events as compared to un-branched TEVAR.

Your risks will vary depending on the circumstances surrounding your procedure; however, possible complications you may experience from the implant procedure or receiving the implanted stent grafts include:

Anesthetic complications	Breakage of any part of the stent grafts
Aortic rupture related to procedure or original aortic disease or injury	Breakage of the delivery catheters
Bleeding during or after the treatment procedure	Breathing difficulty
Blocking the treated branch vessel or another important blood vessel	Bruising
Blood clots in the lungs	Bulging of your blood vessel walls
Bowel complications such as paralysis or temporary lack of bowel motion or decreased blood flow to the intestines	Change in mental status
	Change in the shape or size of the arteries which may cause changes in the stent grafts
	Collapse of the stent grafts

Risks (continued)

Complications with the arteries or veins such as blockage of blood flow in an artery or vein due to blood clotting, vessel rupture or damage to the vessels which could lead to amputation

Complications with the lymph system

Complications with the nervous system such as nerve injury, **stroke** (permanent or temporary), inability to move and/or feel parts of the body, nerve damage in the spine or poor blood supply to the spine resulting in paralysis and/or weakness in the lower extremities

Death

Dysfunction or failure of the kidneys

Erectile dysfunction

Fever

Fistula, an abnormal connection between the aorta and other tissue/organs

Heart complications such as chest pain, irregular heartbeat, inadequate pumping of the heart muscle or heart attack

Inability to get the stent grafts to the correct locations, placing it incorrectly, problems releasing the device from the delivery catheter or problems inserting or removing the delivery catheter

Infection

Infection or blood clots in the stent grafts

Inflammatory reaction to the stent grafts

Leak between the implanted devices or between the implanted devices and your aortic wall, or a leak from a blood vessel into the injured area of your aorta (endoleak)

Risks (continued)

Lengthening of existing aortic dissection
Lung complications such as pneumonia
Metal part of the stent grafts wearing through the artery wall
Movement of the stent grafts within the aorta
Narrowing of blood vessels
Pain due to inadequate blood supply to the heart
Partial or complete collapse of the lungs
Problems with the blood clotting
Radiation injury
Reaction to the x-ray dye used for the angiogram

Reaction to the drug (heparin) used during the procedure
Reoperation (needing another operation)
Rupture or tear (dissection) of the aorta
Stretching and/or breaking of the stent grafts
Swelling of clotted blood within your tissue
Urinary tract issues
Wound complications such as swelling of the leg and infection





Benefits

The main potential benefit to having a branched endovascular repair with a stent graft, compared to non-branched endovascular repair, is that the GORE® TAG® Thoracic Branch Endoprosthesis offers a treatment method that avoids the LSA open surgical procedure and the associated risks.



Follow-up

After endovascular repair with the GORE® TAG® Thoracic Branch Endoprosthesis, follow-up exams will typically consist of a physical examination and imaging, such as a CT scan, to check the repair and evaluate the stent graft performance.

Follow-up will be scheduled with your doctor on a regular basis. Regular follow-ups are required even in the absence of obvious symptoms (e.g., pain, numbness, weakness). These visits commonly occur at one month, six months and annually thereafter.

When should I call my doctor?

Contact your doctor immediately if you experience any of the following symptoms after your procedure:

- Pain, numbness and weakness in the arms, legs, back, chest or abdomen
- Dizziness, fainting, rapid heartbeat or sudden weakness
- Discoloration or coolness of the arms, hands or legs
- Any other unusual symptoms

Other patient considerations

After undergoing an endovascular repair procedure, there are some lifestyle changes that you should be aware of:

- Consult your doctor about your ability to safely perform strenuous physical activities.
- An implanted stent graft typically will not trigger screening or metal detectors, like those at airports or secure building entrances, but consult your doctor about your specific device.
- You should carry your permanent implanted device identification (ID) card in your wallet.

Implanted device identification card

After the procedure, your doctor will give you a temporary implanted device ID card. The card will tell you the size and number of your aortic stent graft implants.

A permanent ID card will be provided later and will list the following information:

- Type of device implanted
- Date of implant
- Your doctor's information
- Magnetic resonance imaging (MRI) information

Be sure to tell all of your healthcare providers that you have the stent graft and show them your implanted device ID card. You should keep your patient ID card available at all times.

Magnetic resonance imaging

It is still safe to have MRI procedures, under certain conditions. MRI information is provided on your implanted device ID card. Before having an MRI, always show your implanted device ID card to your healthcare providers.



Glossary of medical terms

Acute aortic dissection

A phase of dissection occurring within the first 0-14 days.

Aneurysm

A ballooning (thinning and enlarging) of a weakened area of a blood vessel.

Aorta

The main artery (blood vessel) that carries blood from the heart to the rest of the body.

Aortic arch

A part of the main artery (aorta) that connects the ascending aorta with the descending aorta.

Aortic dissection

The tearing of the inner layer of the aortic wall, allowing blood to flow into the wall itself and cause the separation of the inner and outer layers.

Aortic wall

The wall of the aorta is made up of three layers: the thin outer layer, the thick, elastic middle layer and the thin inner layer.

Ascending aorta

An artery that starts in the upper surface of the left ventricle (left side of the heart) and passes upward and turns into the aortic arch.

CT (computed tomography) scan

An imaging technique that uses multiple scans to create a very precise view of your abdomen and aorta — also known as a CAT scan.

Delivery catheter

A long, thin, tube-like tool that assists in the delivery and positioning of a stent graft.

Descending aorta

Part of the main artery (aorta) that begins at the aortic arch and runs down through the chest and abdomen.

Endoleak

When blood from the aorta continues to leak into the thoracic diseased area.

Endovascular repair

A procedure in which a stent graft is placed inside a diseased vessel without surgically opening the tissue surrounding the weakened vessel to exclude (seal off) an aneurysm inside the aorta, making a new path for blood to flow.

Femoral arteries

Two arteries located in each leg, which carry blood to the femur or thigh region of each leg.

Fluoroscopy

A real-time X-ray image that is viewed on a monitor used during endovascular repair.

Iliac arteries

The iliac arteries begin from the bifurcation (separation) of the aorta in your abdomen. These arteries connect the aorta to the femoral arteries delivering blood to the legs.

Left subclavian artery

A main artery that branches off your aorta and supplies blood to your left arm and head.

Magnetic resonance imaging (MRI)

A technique that uses magnetic fields to form images of structures within the body.

Glossary of medical terms (continued)

Malperfusion

Loss of blood supply to a vital organ caused by blood vessel obstruction secondary to a dissection.

Rupture

A tear in the vessel wall near or at the location of the weakened area of the aneurysm allowing blood to flow into the areas around the heart, lungs or abdomen.

Stent graft

A synthetic graft implanted within a weakened blood vessel to exclude (seal off) from the inside. Compressed stent grafts are delivered via catheter to the weakened area, and once positioned, expanded to fit the size of the vessels in which it is placed.

Stroke

Damage to the brain from interruption of its blood supply.

Synthetic graft

A man-made material in tube form intended to replace damaged blood vessels.

Thoracic aorta

The part of the aorta that is located in the chest.

Thoracic aortic aneurysm (TAA)

A ballooning (enlarging and thinning) of the aorta due to a weakening in the arterial wall that occurs in the chest area.

Traumatic aortic transection (Transection)

A tear in the aorta that usually occurs in the chest, often referred to just as a transection.



Where can I get more information?

Background Information on thoracic disease

American Heart Association	heart.org
Society for Vascular Surgery	vascular.org/patients

Interventional therapy

Society of Interventional Radiology	sirweb.org
U.S. National Library of Medicine	medlineplus.gov

Product Information

W. L. Gore & Associates, Inc.	goremedical.com/conditions
U.S. Department of Health and Human Services Food and Drug Administration	fda.gov

Questions for my doctor

You and your doctor should review the risks and benefits when discussing this stent graft and procedure including:

- Risks and differences between the TBE device (branched TEVAR) and non-branched TEVAR.
- Potential advantages of non-branched TEVAR.
- Potential advantages of branched TEVAR.
- The possibility that additional endovascular treatment or surgery may be required after initial endovascular repair.

In addition to the potential risks and benefits of an endovascular repair, your doctor should consider your commitment to and compliance with post-operative follow-up as necessary to ensure continuing safe and effective results.

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 Consult Instructions
for Use
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Indications for use in the U.S.: The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who are at high risk for debranching subclavian procedures and have: **Adequate iliac/femoral access; Proximal Aortic Landing Zones:** For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified, or heavily thrombosed; For Dissection Patients: Primary entry tear must be distal to the left subclavian artery and the proximal extent of the landing zone must not be dissected; Aortic inner diameter range 16–42 mm; Proximal segment length (length from distal edge of left subclavian artery to mid left common carotid ostium) of at least 2.0–4.0 cm, depending on Aortic Component selection; Proximal covered length (measured from distal edge of left subclavian artery to distal edge of left common carotid artery ostium) of at least 15–36 mm, depending on Aortic Component selection; For patients with prior ascending aorta or aortic arch repair with surgical graft: at least 2 cm landing zone proximal to the distal anastomosis; **Left Subclavian Landing Zone:** Not aneurysmal, dissected, heavily calcified, or heavily thrombosed and without severe tortuosity (180 degree turn within the treated length); Left subclavian artery inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected; Left subclavian artery minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected. **Distal Landing Zone (Isolated Lesion Patients only):** Outer curve length must be ≥ 2 cm proximal to celiac artery; Aortic inner diameter range 16–42 mm; Non aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone; Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft. **Contraindications:** The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials [ePTFE (polytetrafluoroethylene), FEP (fluoroethylpropylene), Nitinol (nickel, titanium), Gold, SB Component only – Heparin (CBAS® Heparin surface)]; Patients who have a condition that threatens to infect the graft; Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Rx Only

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